K032394

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510(k) Summary for Stryker Spine Oasys System

Proprietary Name:	Stryker Spine Oasys System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	Spinal Interlaminal Fixation Orthosis 21 CFR 888.3050 Pedicle Screw Spinal System 21 CFR 888.3070
Proposed Regulatory Class:	Class II
Device Product Code:	87 KWP: Appliance, Fixation, Spinal Interlaminal 87 MNI: Orthosis, Spinal, Pedicle Fixation
For Information contact:	Karen Ariemma Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Telephone: (201) 831-5718 Fax: (201) 831-6038 Email: kariemma@howost.com
Date Summary Prepared:	December 18, 2003

Device Description

The Stryker Spine Oasys System is comprised of rods, polyaxial screws, bone screws, hooks, connectors, and an occiput plate. The components are available in a variety of lengths in order to accommodate patient anatomy. The components are fabricated from titanium alloy. The components will be provided non-sterile.

Intended Use

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput –T3), the Stryker Spine Oasys System is intended for: Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); Spondylolisthesis; Spinal Stenosis; Fracture/Dislocation; Atlanto/axial fracture with instability; Occipitocervical dislocation; Revision of previous cervical spine surgery; and Tumors.

When used with the occipital plate the bone screws are limited to occipital fixation. The bone screws are not intended to be used in the cervical spine.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The Stryker Spine Oasys System can also be linked to the Xia Spinal System via the rod to rod connector.

Substantial Equivalence

Equivalency of this device is based on similarities in intended use, materials, and design to other currently marketed posterior occipito-cervico-thoracic spine systems. Mechanical testing demonstrated comparable mechanical properties to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Ms. Karen Ariemma
Regulatory Affairs Specialist
Stryker Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401-1677

Re: K032394
Trade Name: Styker Spine OASYS System
Regulation Number: 21 CFR 888.3050
Regulation Number: 21 CFR 888.3070 (b) (1), 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis
Product Code: MNI, KWP
Dated: December 18, 2003
Received: December 19, 2003

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033394

510(k) Number (if known): K033394

Device Name: Stryker Spine Oasys System

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for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number K033394

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___ (Per 21 CFR 801.109)
(Optional Format 1-2-96)